REMARKS

The present document is submitted in response to the Office Action dated May 25, 2010 ("Office Action").

Claims 1-31, 38-53, 67-69, 75 and 76 were previously pending in this application. Among them, claims 10, 19-23, 30, 31, 47, and 67-69 have been withdrawn from consideration.

By this amendment, Applicant has amended claims 1 and 3, support for which appears in, e.g., original claim 14. This amendment has necessitated cancellation of claims 14, 15, 18, 27, and 29; and dependency changes to claims 16, 19, 28, and 30. Further, Applicant has amended claims 42-44 to further clarify the claimed subject matter and cancelled claim 13. These amendments have not introduced new matter.

Upon entry of the amendments summarized above, claims 1-9, 11, 12, 16, 17, 24-26, 28, 38-46, 48-53, 75, and 76 will be under examination. Applicant respectfully requests that the Examiner reconsider this application in view of the following remarks.

Rejections under 35 U.S.C. §112, Second Paragraph

Claim 13 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Office Action, page 2. Cancellation of this claim has rendered this rejection moot.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-9, 11-16, 18, 24-27, 29, 38-40, 42-43, 45-46, 48-53, and 75-76 are rejected under 35 U.S.C.§112, first paragraph, as allegedly failing to comply with the enablement requirement. Office Action, pages 2-3. More specifically, the Examiner assertes that the rejected claims are not enabled as they fail to point out the antigen specificity of the immunoglobulin required by them. Office Action, page 3, fifth paragraph. Applicant respectfully disagrees.

As set forth in MPEP § 2164.01, a claimed invention is enabled if "any person skilled in the art can make and use the invention without undue experimentation," citing *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). This is exactly the case here.

In the present application, the rejected claims, as amended, are related to a plant-produced IgA immunoglobulin that has a glycopeptides profile including at least one glycopeptide that lacks fucose. Clearly, "plant-produced" and "glycosylated with reduced fucose content" are essential features of the IgA immunoglobulin required by the claims at issue.

Regarding the how-to-make prong of the enablement requirement, the specification provides a general and adequate description on how to produce IgA molecules in plants. Pages 17-23, paragraphs [0291] to [0368]. Further, it provides a specific example of producing an anti-herpes simplex virus (HSP) antibodies in plants. Examples 1-6. As shown in Figure 12, this plant-produced antibody is glycosylated with various glycan moieties, a number of which lacks fucose. Page 34, paragraph [0466]. In view of the general description and the specific example provided in the specification, a skilled person in the art would readily know how to produce in plants any IgA immunoglobulin, regardless of its antigen specificity. For example, one can use the same method as taught in the specification for producing the specific anti-HSP IgA antibody to produce another IgA antibody with a different antigen-specificity in plants. In other words, no undue experimentation would be needed to make the IgA immunoglobulin required by the claims in its entire scope, which is plant-produced and glycosylated with reduced fucose content.

Turning to the how-to-use prong, Applicant points out that it is within the knowledge of a skilled artisan to use each individual IgA immunoglobulin within the scope of the rejected claims, based on the antigen-specificity of that individual IgA. In other words, no undue experimentation would be needed to use the IgA immunoglobulin required by the claims in its entire scope.

In sum, a skilled person in the art, in view of the teachings in the specification and common knowledge, would know how to make and use the IgA immunoglobulin required by the claims at issue in its entire scope without undue experimentation. Pursuant to MPEP § 2164.01 quoted above, all of the rejected claims are enabled. Withdrawal of this rejection is therefore respectfully requested.

Rejections Under 35 U.S.C. §102

Claims 1-9, 11-15, 18, 24-26, 29, 45-46, and 48-53 are rejected under 35 U.S. C. §102(b) as allegedly being anticipated by Elbers et al., Plant Physiology, 126:1314-1322, 2001 ("Elbers").

The rejected claims, as amended, are drawn to a plant-produced immunoglobulin or a heavy chain or light chain of the immunoglobulin having a glycopeptides profile containing at least one glycopeptide that lacks fucose. The claims at issue further require that the immunoglobulin be an IgA.

Elbers discloses transgenic tobacco expressing a mouse immunoglobulin G (IgG) antibody, i.e., MGR48. Abstract and page 1319, right column, third paragraph. As explicitly pointed out by the Examiner, this reference did not teach "that the antibody is an IgA or a human antibody." Office action, page 5, last paragraph. Thus, it does not anticipate the claims under consideration, all of which require an IgA antibody.

For at least the foregoing reason, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 14-17, 27-28, 38-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over Elbers in view of Mayfield et al., US 2004/0014174 ("Mayfield").

The rejected claims, all dependent from claim 1 or 3, are also directed to a plant-produced IgA immunoglobulin or a heavy chain or light chain of the IgA. These claims require that the antibody has a glycopeptides profile containing at least one glycopeptide that lacks fucose. In view of this requirement, a skilled person in the art would readily understand that the claimed IgA immunoglobulin or a heavy/light chain thereof is glycosylated with reduced fucose content.

Elbers, as discussed above, discloses a transgenic plant that expresses a mouse IgG antibody. Mayfield discloses producing polypeptides, e.g., an IgA antibody in plant chloroplasts. In view of Elbers and Mayfield, the Examiner concludes that the combination of these two references renders the claimed invention *prima facie* obvious. Office Action, page 6, third paragraph. Applicant respectfully disagrees for at least two reasons.

First, the IgA antibody taught in Mayfield is a single-chain antibody expressed in plant chloroplasts. Paragraph [0018]. According to Mayfield, polypeptides expressed in plant chloroplasts "are not subject to certain post-translational modifications such as glycosylation." Paragraph [0087]. Thus, unlike the claimed plant-produced IgA molecule or its heavy/light chain, the single-chain IgA antibody taught in Mayfield, expressed in chloroplasts, is non-glysocylated.

Elbers, as pointed out above, does not mention any IgA antibody required by the claims under examination. Thus, the combination of Mayfield with Elbers would not have arrived at these claims, all of which require an IgA immunoglobulin that is glycosylated but with low fucose content.

Second, Mayfield explicitly teaches that an advantage of the invention disclosed in it is to produce non-glycosylated polypeptides (e.g., a single-chain IgA antibody) in plants as such polypeptides can be expected to be less antigenic. Paragraph [0087]. This teaching indeed would have discouraged a skilled artisan from producing in glycosylated IgA immunoglobulins, as required by the claims under examination.

In view of the above remarks, Applicant submits that Elbers and Mayfield, either taken alone or in combination, do not render the claimed invention obvious. Withdrawal of this rejection is therefore respectfully requested.

CONCLUSION

For the reasons set forth above, the present application is in condition for allowance. Favorable consideration is therefore respectfully solicited.

Please charge our Credit Card in the amount of $ 1,110 covering the time extension fee set forth under 37 CFR 1.17(a)(3). The Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed, or that should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. P0850.70005US01.

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Respectfully submitted,

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